

REMARKS

Upon entry of the amendments herein, claims 1, 2, 4, 7, 9, 10, 12, 13 and 27-34 are pending in the application. No amendments have been made herein to the previously pending claims; however, new claims 31-34 have been added. No new matter has been introduced by these new claims.

Applicants and the undersigned acknowledge with gratitude the time taken by Examiner Desai on September 20, 2005 to discuss various issues and to reach a clearer understanding of the relationship between the presently claimed subject matter and that allowed in the previously filed applications in this family. Much of the presentation following is reflective of the issues discussed.

The rejection of claim 1 as being nonenabled was maintained in the present Office Action. As pointed out to the Examiner during the September 20<sup>th</sup> discussion, it is the relationship between the claimed subject matter of the instant application and that allowed in the **grandparent** application (Serial No. 09/171,570, now U.S. Patent No. 6,479,497) that is important, not the relationship between the instantly claimed subject matter and that allowed in the **parent** (Serial No. 10/285,743, now U.S. Patent No. 6,670,359). The claims allowed in the parent application are all directed to compounds wherein X is CH, whereas the claims in the present application are all directed to compounds wherein X is N. Accordingly, there is no

conceivable possibility of overlapping subject matter and no possibility that any of instantly claimed subject matter could be encompassed by any of the restriction groups set forth in the parent by the Examiner.

On the other hand, as pointed out to the Examiner, the claims allowed in the grandparent application (now U.S. Patent No. 6,479,497) are directed to compounds wherein X is N and are limited to such. However, they are also narrower with respect to the original scope of many of the other substituents, including substituent R<sub>4</sub>. In the '497 patent, when R<sub>4</sub> is a heterocyclic or heteroaromatic ring, it must be a 5- or 6-membered ring and the one or both heteroatoms must be N. This is clear from an examination of claim 1 of the '497 patent.

On the other hand, the claims of the present application recite compounds of formula I wherein X is N that were excluded by the Examiner's restriction as to substituent R<sub>4</sub> in the grandparent application (now the '497 patent). The present claims recite none of the R<sub>4</sub> heterorings found in the claims of the '497 patent. As pointed out to the Examiner during the September 20, 2005 discussion, and as the Examiner indicated she understood, the present claims are directed to compounds wherein R<sub>4</sub> can only be a heterocyclic or heteroaromatic ring and these rings are defined to specifically exclude the 5- and 6-membered rings possible in the claims of the '497 patent.

As further pointed out to the Examiner, and as she also

indicated she understood, the disclosure on page 5, lines 14-25 and various of the examples (including Examples 34 and 35 containing a 7-membered heterocyclic ring) set forth a number of heterocyclic and heteroaromatic rings that  $R_4$  can be which are not encompassed by the claims allowed in the '497 patent but which are encompassed by the definition of  $R_4$  in the present claims. In other words, the  $R_4$  heterorings of the present claims that are 5- and 6-membered are ones wherein when there is a single heteroatom, it is S or O (i.e., not N) and when the heteroring contains two heteroatoms, at least one of them is not N (i.e., is S or O), and there is adequate exemplification of such rings in the specification.

The Examiner states on page 2 of the Action: "There is no disclosed species, other than the ones claimed in the parent." [Emphasis added.] Again, the Examiner has confused the relationships among the claimed subject matter of the present application and that of the claims in the two allowed prior applications. There are no claims reciting compounds wherein X is N in the '359 patent (which issued from the parent) and, thus, the comparison between the definition of  $R_4$  in the claims of the '359 patent and the definition of  $R_4$  in the present claims is immaterial. The comparison must be made between  $R_4$  in the claims of the '497 patent (which issued from the grandparent) and  $R_4$  in the present claims. There clearly are disclosed species other than the ones claimed in the '497 patent, and

there is adequate written description as to what these other heterorings are.

The rejection of claims 13, 27 and 28 as being indefinite was also maintained. In the present Office Action, the Examiner made no comment on Applicants' previous response, wherein they pointed out that claims of identical form to the present claims in question had been allowed, by the same Examiner, in both the parent and grandparent applications. In the September 20, 2005 discussion, the Examiner advised that it is now general Office policy not to allow so-called "reach-through" claims. This is the current policy, apparently, even though there is no precedent in terms of Court decisions, nor is there any basis in current patent law for such a stance.

In trying to justify this rejection, the Examiner states: "Drugs also do no [sic] act as agonists and antagonists. It is either one or the other. Thus drugs that treat depression may not be able to treat anxiety." The Examiner further suggests limiting treatment to depression. Applicants do not understand what the Examiner's basis for the statements is.

As disclosed in the instant specification and as is well known in the field, changes in 5-HT neurotransmission can have an effect on both depression and anxiety; an increase in 5-HT activity is associated with anxiety, while a decrease in activity has been associated with depression (specification, page 1, line 23 to page 2, line 4). It is also disclosed (page

3, lines 7 and 8) that the compounds according to the instant invention may, in their binding to the h5-HT<sub>1B</sub> receptor, be divided into ones acting as full agonists, partial agonists or antagonists. This is why the broadest claims, rightfully, are not limited to antagonism but instead recite disorders mediated by 5-HT and the receptor in question.

Again, there is much precedent, even in this very application family, for the allowability of method claims of the form of instant claims 13, 27 and 28; and there is no valid precedent whatsoever for rejecting such claims as being "reach-through." Furthermore, Applicants maintain that the reasons given by the Examiner on page 2 of the Action in an attempt to justify the rejection are without merit. Accordingly, these claims have been maintained in their previous form.

In addition, however, new method claims 31-34 have been added. These claims cannot in any way be construed as "reach-through," and claims 31 and 32 in particular also reflect the idea disclosed in the present specification, and accepted in the field, that compounds of the type found in the instantly claimed genus might manifest properties as either antagonists or agonists of the receptor in question. Support for these claims can be found in the specification in, for example, the passage running from page 1, line 23 to page 2, line 4 and that on page 3, lines 7 and 8. Claims 33 and 34 are directed to a particular embodiment of the invention, namely, treatment of depression.

The entry of these new claims was not discussed with the Examiner; however, they are directed to patentable subject matter and should be allowed.

The obviousness-type double patenting rejection of the claims over U.S. Patent No. 6,479,497 (again, the patent that issued from the **grandparent** of the present application) was also maintained. The Examiner refers to Applicants' previous amendment to change the language of the definition of substituent  $R_3$  from "may be mono- or di-substituted with  $R_4$  and/or  $R_5$ " to "is monosubstituted with  $R_4$  or disubstituted with  $R_4$  and  $R_5$ " and asserts that this is inadequate to overcome the previous rejection, further stating that "[E]ven the hetero substitutions on the phenyl  $R_3$  are encompassed by the prior patent." The Examiner goes on to set out the restriction requirement leveled in the parent application and concludes that "applicants seem to have elected group III over again." As explained to the Examiner during the discussion, and as the Examiner indicated she understood, this assessment is in error.

Again, the full prosecution history of this application family and the various restrictions imposed must be taken into consideration. When taken on its own, the restriction requirement cited by the Examiner, the one she leveled in the parent application, is really not relevant to the consideration of patentability at hand. In the first place, there is an Examiner's note at the end of restriction group III:

"[Applicants elected a species as given on page 6 lines 16-17]."

This is a reference to a specification passage and, as can be seen from that passage, the species the Examiner refers to is one in which X is CH. Thus, again, none of the compounds in restriction group III in the parent can be found among the compounds encompassed by the present claims.

One must go back to the restriction requirement leveled in the grandparent to appreciate the relevant relationship between the presently claimed compounds and those previously allowed. In the grandparent, the Examiner first required segregation of compounds wherein X is N from compounds wherein X is CH and then imposed further restrictions within those restriction groups as to the scope of some of the other substituents. In the end, after considerable discussion and clarification, the Examiner was only willing in the grandparent application to allow claims directed to compounds wherein X is N and wherein the scope of substituent R<sub>4</sub> when R<sub>4</sub> is a heteroring was greatly restricted from the scope of heterorings encompassed in the original definition of R<sub>4</sub>. This can clearly be seen from claim 1 of the '497 patent, which issued from the grandparent.

Again, the present application exists only because of the restrictions imposed by the Examiner. It was filed to introduce claims directed to compounds wherein X is N that were restricted out of, and not allowed in, the grandparent application and are thus not claimed in the '497 patent, which issued from that

application. These compounds consist of ones wherein substituent R<sub>4</sub> is a heterocyclic or heteroaromatic ring that is not encompassed by the narrow definition of R<sub>4</sub> heterorings in the claims of the '497 patent. Thus, Applicants are not presently claiming any subject matter that was allowed in either the grandparent or parent application, but are instead claiming subject matter supported by the instant specification and originally claimed that was restricted out during prosecution of the grandparent and parent applications. During the September 20, 2005 discussion, the Examiner indicated that this was now clear.

It cannot be emphasized enough that the present **divisional** application exists only because of the Examiner's opinion in the grandparent that the originally claimed subject matter comprised various distinct inventions. In the grandparent application, the Examiner held that the compounds now under examination constitute a separate invention from the compounds ultimately allowed in said grandparent. Again as shown above, and as confirmed by the Examiner's own analysis, the currently claimed compounds and those claimed in the '497 patent are distinct from each other. The rules are clear that a divisional in such a case cannot be the object of an obviousness-type double patenting rejection over any application from which it arose or over any patent that issued from such a predecessor application. This rejection must be withdrawn.



The obviousness-type double patenting rejection of claims 1, 2, 4, 7, 9, 10, 12, 13 and 27-30 over U.S. Patent No. 6,387,899 was also maintained. This issue was not a part of the September 20, 2005 discussion.

Applicants note that, despite the maintaining of this rejection, the obviousness-type double patenting rejection of claim 30 over U.S. Patent No. 6,384,225 was withdrawn. The issue in the two rejections was exactly the same, and the former rejection should have been withdrawn as well. On page 5 of the present Action, the Examiner has duplicated part of claim 1 of the '899 patent and states that "there is clearly overlapping subject matter" with that of the present claims.

Applicants do not disagree with the assessment that the definitions of X, Y, R<sub>1</sub> and R<sub>3</sub> in claim 1 of the '899 patent encompass the definitions of those substituents in the present claims. However, the Examiner has failed to notice the fact that the benzo portion of the benzopyran (chroman) structure of formula I of claim 1 of the '899 patent has a second substituent, R<sub>9</sub>, and that this substituent cannot be H. The compounds of instant claim 1 have no such substituent whatsoever, and there clearly is no overlapping subject matter between the two generic formulae. It certainly cannot be said that it is obvious to remove substituent R<sub>9</sub> from the compounds of claim 1 of the '899 patent to arrive at the compounds claimed in the present application. It should also be noted that, as was

appropriate, no issues of obviousness-type double patenting over the '899 patent were ever raised by the Examiner during prosecution (to allowance) of the two predecessors to the instant application. The filing of a Terminal Disclaimer is not warranted. This rejection must be withdrawn, just as the previous rejection of claim 30 over the '225 patent was withdrawn.

In view of the understanding reached during the discussion and in view of the further explanations and arguments set forth herein, it must be clear to the Examiner that there is no overlap between the instantly claimed subject matter and that found in the claims of the patents that issued from the parent and grandparent applications. It must also be clear that the instantly claimed subject matter is patentably distinct over that found in claim 1 of coassigned U.S. Patent No. 6,387,899. Furthermore, the present claims meet the statutory requirements with respect to definiteness and enablement. Reconsideration and allowance of the application with pending claims 1, 2, 4, 7, 9, 10, 12, 13 and 27-34 are respectfully requested. The Examiner indicated during the discussion that, should any present issues remain and/or any further questions arise, she would contact the undersigned by telephone prior to issuing a formal Office Action. Such consideration is also respectfully requested.

No additional fees should be due in connection with this communication. However, should it be determined that such a fee is required for any reason, the Commissioner is hereby authorized to charge it to Deposit Account No. 23-1703.

Dated: September 22, 2005

Respectfully submitted



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